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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|----------------------------------------------------------------------|----------------|------------------------------|---------------------|------------------|--|
| 09/830,227 | 06/11/2001 | C.M. Cornelis Marius Timmers | 0/98411 US | 3269 | |
| 75 | 590 08/13/2003 | | | | |
| William M. Blackstone Patent Department/Invert Inc. 405 State Street | | | EXAMINER | | |
| | | | TRUONG, TAMTHOM NGO | | |
| Mllsboro, DE | 19900 | | ART UNIT | PAPER NUMBER | |
| | | | 1624 | | |

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

| | | Applicati n N . | Applicant(s) | Applicant(s) | | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------------------------------------------|----------------|--|--|--|
| Office Action Summary | | 09/830,227 | TIMMERS ET AL. | TIMMERS ET AL. | | | |
| | | Examin r | Art Unit | | | | |
| | | Tamthom N. Truong | 1624 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period f r Reply | | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | | |
| Status 1)⊠ | Responsive to communication(s) filed on 27 M | May 2003 | | | | | |
| 2a)⊠ | | s action is non-final. | | | | | |
| , | , — | | ra processition as to th | o monito io | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims | | | | | | | |
| 4)⊠ Claim(s) <u>1-10</u> is/are pending in the application. | | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | |
| 5)⊠ Claim(s) <u>1-6 and 10</u> is/are allowed. | | | | | | | |
| 6)⊠ Claim(s) <u>9</u> is/are rejected. | | | | | | | |
| 7) | Claim(s) is/are objected to. | | | • | | | |
| 8)□ | Claim(s) are subject to restriction and/or | election requirement. | | | | | |
| Application Papers | | | | | | | |
| 9)□ T | 9)☐ The specification is objected to by the Examiner. | | | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | | |
| | Applicant may not request that any objection to the | | | | | | |
| 11)□ T | 11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner. | | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | | |
| 12)☐ The oath or declaration is objected to by the Examiner. | | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | | |
| a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | | |
| Attachment(s) | | | | | | | |
| 1) Notice | of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948) ation Disclosure Statement(s) (PTO-1449) Paper No(s) | 5) Notice of Info | nmary (PTO-413) Paper No(mal Patent Application (PTC | | | | |

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FINAL ACTION

Applicant's amendment of 5-27-03 has been fully considered. The amended claims have overcome the previous rejection of 112/2nd paragraph. Because the cancellation of claim 9 is only mentioned in the "REMARKS", which is not counted as part of the "amendment", and therefore, has not been entered.

Examiner Truong has contacted Mr. William Blackstone on 8-11-03 regarding the nonentry of claim 9, and the potential reference of the US equivalent of WO 99/47503.

Thus, the enablement rejection on claim 9 remains outstanding.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement: Claim 9 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the active compounds of formula I, does not reasonably provide enablement for their prodrugs. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The rejection is maintained for the reason stated in the previous action.

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Allowable Subject Matter

Claims 1-6, and 10 are allowed. Except for the US equivalent of WO 99/47503, currently there is no reference reading on said claims. The relevance of said US equivalent cannot be determined right now since it has just been allowed, but not yet published.

Reference cited on PTO-892

An update search yields a reference of WO 99/47503, which appears to bear relevant subject matter. Because its publication date does not antedate the priority date claimed herein, it is not a competent prior art. However, its corresponding US application has just been allowed, and could be prior art. Applicant is suggested to review WO'503, particularly intermediates #23, 24, and 26 on pages 11 and 12.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9:30-5:00) & every Saturday morning (starting from 4-7-03).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

T. Truong

August 11, 2003

MUKUND J. SHAH
SUPERVISORY PATENT EXAMINER
GROUP 1200